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APPLICATION NUMBER: ***60/555,515***
FILING DATE: ***March 23, 2004***
RELATED PCT APPLICATION NUMBER: ***PCT/US05/09835***

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

Express Mail Label No.: EV 415945674 U.S.

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Dennis	Soerensen	Atlanta, Georgia USA
Ajit	Yoganathan	Tucker, Georgia USA

☐ *Additional Inventors are being named on the _____ separately numbered sheets attached hereto.*

TITLE OF THE INVENTION (280 characters max)

2-INLET 2-OUTLET CONNECTION FOR OPTIMIZED FLOW CONTROL AND MINIMIZED ENERGY LOSS

CORRESPONDENCE ADDRESS

☐ Customer Number or Bar Code Label (Insert Customer No. or Attach bar code label here) Or ☒ Correspondence address below

NAME	**Office of Technology Licensing** **Georgia Tech Research Corporation** **Attention: Director**				
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ENCLOSED APPLICATION PARTS (*check all that apply*)

☒ Specification *Number of Pages* 7 ☐ CD(s), Number _____

☒ Drawing(s) *Number of Pages* 0 ☒ Other (Specify) Return postcard

☒ Application Data Sheet. See 37 CFR 1.76.

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27

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Respectfully submitted,
GEORGIA TECH RESEARCH CORPORATION

SIGNATURE: Kimberly Dunn

TYPE or PRINTED NAME: Kimberly Dunn,
Patent Coordinator

Date: March 23, 2004

Docket No.: 3080 PR

REGISTRATION NO.:

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

PATENTS
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Soerensen, et al.

For: **2-INLET 2-OUTLET CONNECTION FOR OPTIMIZED FLOW CONTROL AND MINIMIZED ENERGY LOSS**

CERTIFICATE OF EXPRESS MAIL FOR PROVISIONAL APPLICATION

Assistant Commissioner for Patents
Box PROVISIONAL PATENT APPLICATION
Washington, D.C. 20231

Sir:

Enclosed for filing in the above case are the following documents:

Provisional Application Patent Cover Sheet
Provisional Application
Fee Transmittal Form
Provisional Application Filing Fee, Small Entity - $80.00
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Respectfully submitted,

Kimberly Dunn

Kimberly Dunn,
Patent Coordinator

GEORGIA TECH RESEARCH CORPORATION
OFFICE OF TECHNOLOGY LICENSING
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Our Reference No: **3080 PR**

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Background of the invention

2 out of 1000 births are born with a single ventricle. Surgical repairs that separate the pulmonary and systemic circuits, placing them in series with the univentricular pump, termed 'Fontan repairs' are palliative, and unfortunately not curative. Operations are routinely staged over many years and survivors often require a lifetime (rather limited) of intensive medical attention. Clinicians report that their patient populations with this complex cardiovascular physiology require a disproportionate share of their time. Many of the complications are related to the gastrointestinal system. These include feeding disorders, liver dysfunction and protein losing enteropathy. Although the causes for these complications are multi-factorial, high systemic venous pressure is an important physiologic factor.

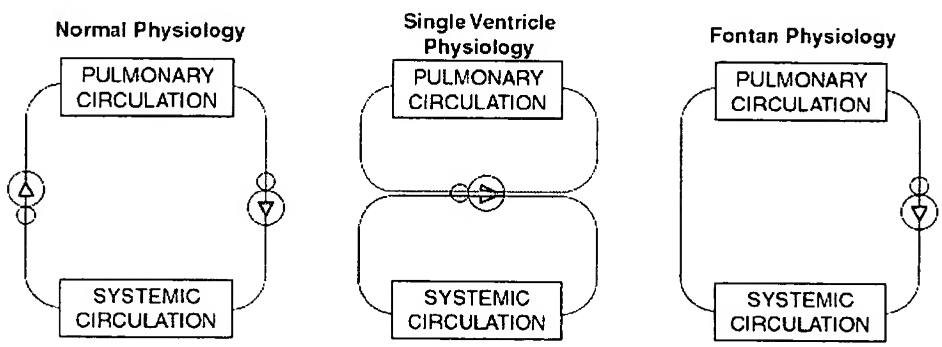

Fig. 1. Schematic showing differences between normal, single ventricle, and Fontan physiology.

In a normal physiology, the vena cavae contains deoxygenated blood coming from the systemic circulation and the pulmonary arteries (PA) carries blood from the right ventricle to the lungs for the blood to become oxygenated.
The single ventricle physiology pumps high pressure blood to both the systemic and the pulmonary circulation. The high pressure in the pulmonary circulation causes a lot of problems, which is why the Fontan procedure is performed.
The Fontan procedure includes a connection of the two pulmonary arteries and the two vena cavae. The left pulmonary artery (LPA), the right pulmonary artery (RPA), the superior vena cava (SVC), and the inferior vena cava (IVC) are all connected, guiding the deoxygenated blood from the systemic circulation to the lungs.
The current Fontan surgical procedure of choice for patients with single ventricle physiology is the total cavopulmonary connection (TCPC). There are two versions of the TCPC namely, extracardiac and intraatrial.
Both extracardiac and intraatrial TCPC yields high energy losses in the blood flow because of the mixing of the blood. Fig. 2 and 3 shows models of the TCPC with a transparent blood analogue containing particles flowing through the connection. The 2 inlets (SVC and IVC) and the 2 outlets (RPA and LPA) are shown in different configurations. As can be seen from the two figures, there is a lot of swirling when the blood analogue from the inlets mix, which causes substantial energy loss, causing the flow to loose momentum towards the lungs. This is a major problem with the current models used for Fontan procedures.

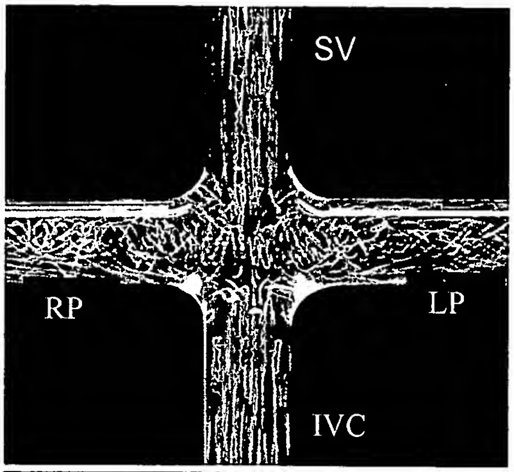

Figure 2 - In Vitro glass model of a "zero" offset TCPC

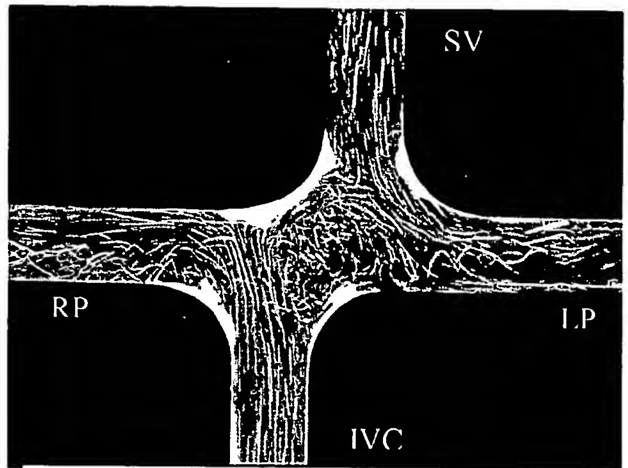

Figure 3 - In Vitro model of a 1-diam. offset and flared model of Cavopulmonary Connection

Other models have been tested to see if they would decrease the energy losses in the connection.

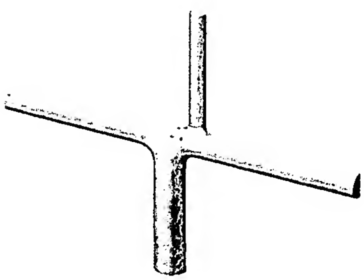

Figure 4 – One diameter offset planar TCPC model. SVC and IVC diameters are more representative of the in vivo dimensions.

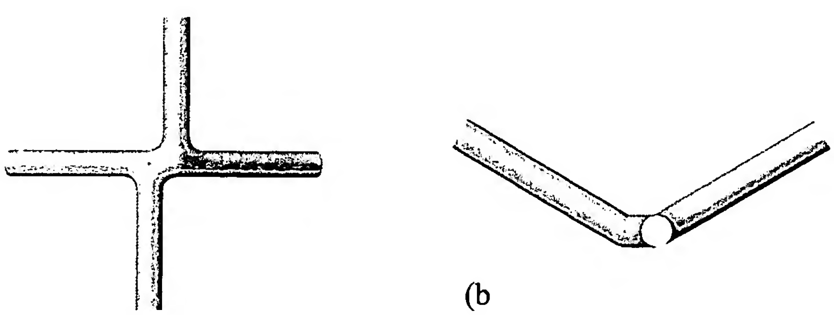

Figure 5 – TCPC model incorporating non-planar arrangement of pulmonary arteries. This model also incorporates a one diameter caval offset; however, all vessels were assumed to be the same size.

RPA/LPA flow splits of 30/70, 40/60, and 50/50 in the above models have shown that when equally much flow goes to the two PA's is when there is least energy loss in the flow. Furthermore, the more different the diameters are in the SVC and the IVC the more energy loss in the flow. The Fontan made today, typically resembles a mix of figures 4 and 5, giving substantial energy losses. Experimentally the model in fig. 3 shows good results compared to the others. There is just one problem: Nutritious blood coming from the hepatic veins goes primarily to one lung, increasing the size and functionality of this lung compared to the other lung.

Summary of the invention

The OptiFlo connection provides optimal flow, reducing the energy loss to a minimum, and it provides an equal amount of hepatic blood to both lungs. It also provides a clinician with the entire control of how the blood distribution throughout the connection should be. The way the blood distribution is controlled is by varying diameters of the vessels in the connection.
The connection can be made of graft material, original blood vessels, or both.
Below is shown illustrations of the OptiFlo model.

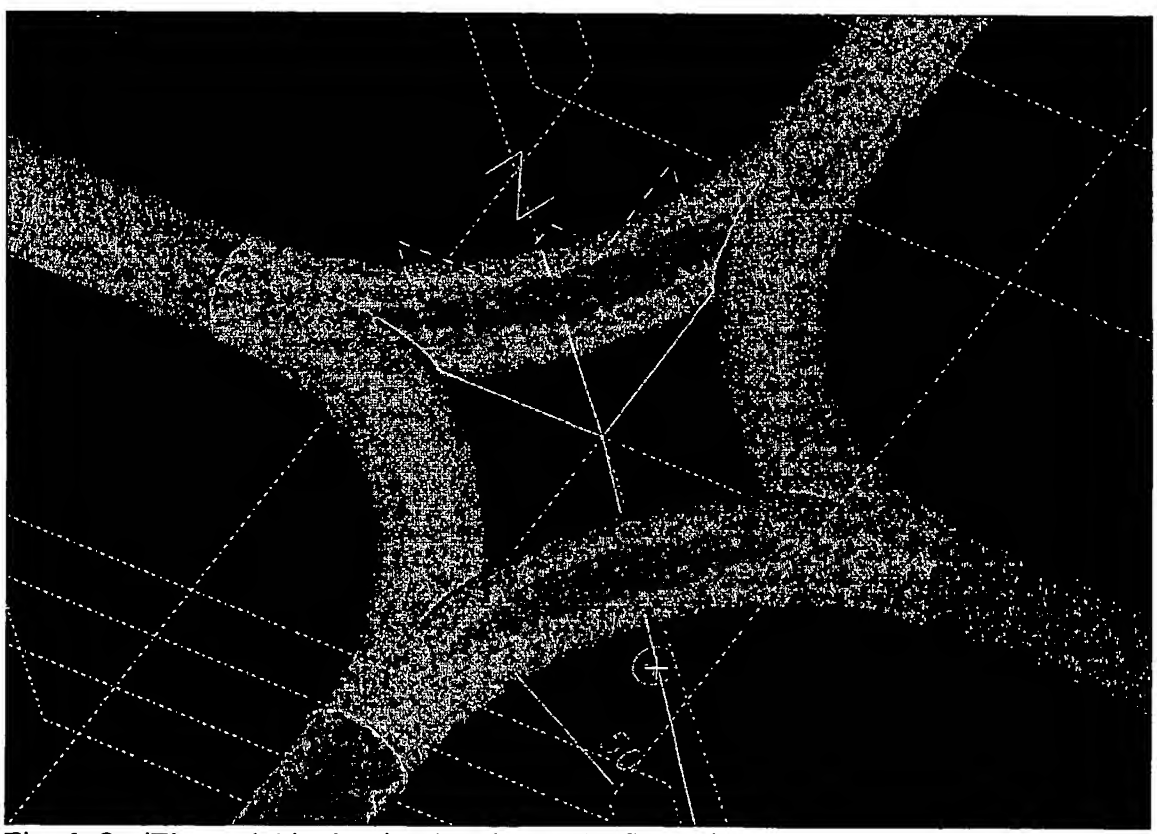

Fig. 6. OptiFlo model in the simplest form. The flow will enter in two opposite vessels and exit in the other two vessels, which are also opposite to each other.

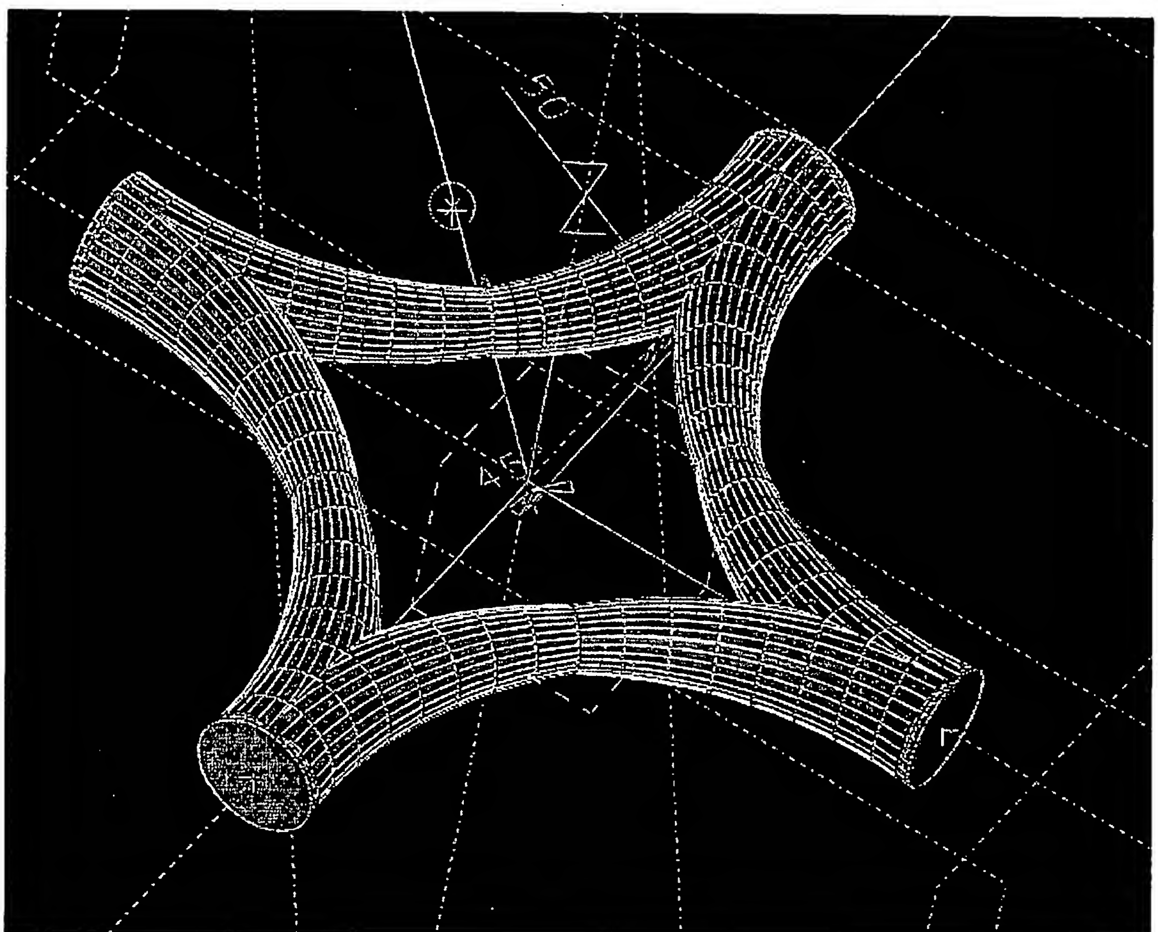

Fig. 7. OptiFlo model with vessel diameters changed in the connection.

The vessel diameters change in fig. 7. As mentioned above, changing the vessel diameters changes the flow and pressure distribution. By increasing some vessel diameters and decreasing other vessel diameters, the blood can be more or less redirected where it is wanted.

The patent should cover all sorts of geometries that consist of the following:

Two inlets, opposite of each other, each split into two splits, where after these splits merge into two outlets, which will be opposite of each other.

The geometries include offset between the vessels, vessels that curve and are not necessarily in the same plane, and vessels entering and exiting with different diameters.

The First Promising Results

We have now conducted several experiments showing that the OptiFlo connection indeed improves the flow considerably compared to the connections shown in figures 2-5 above. Using MRI we have acquired this flow field where the arrows shown are velocity vectors of the water/glycerin fluid that flows through the connection acting as a blood analogue.

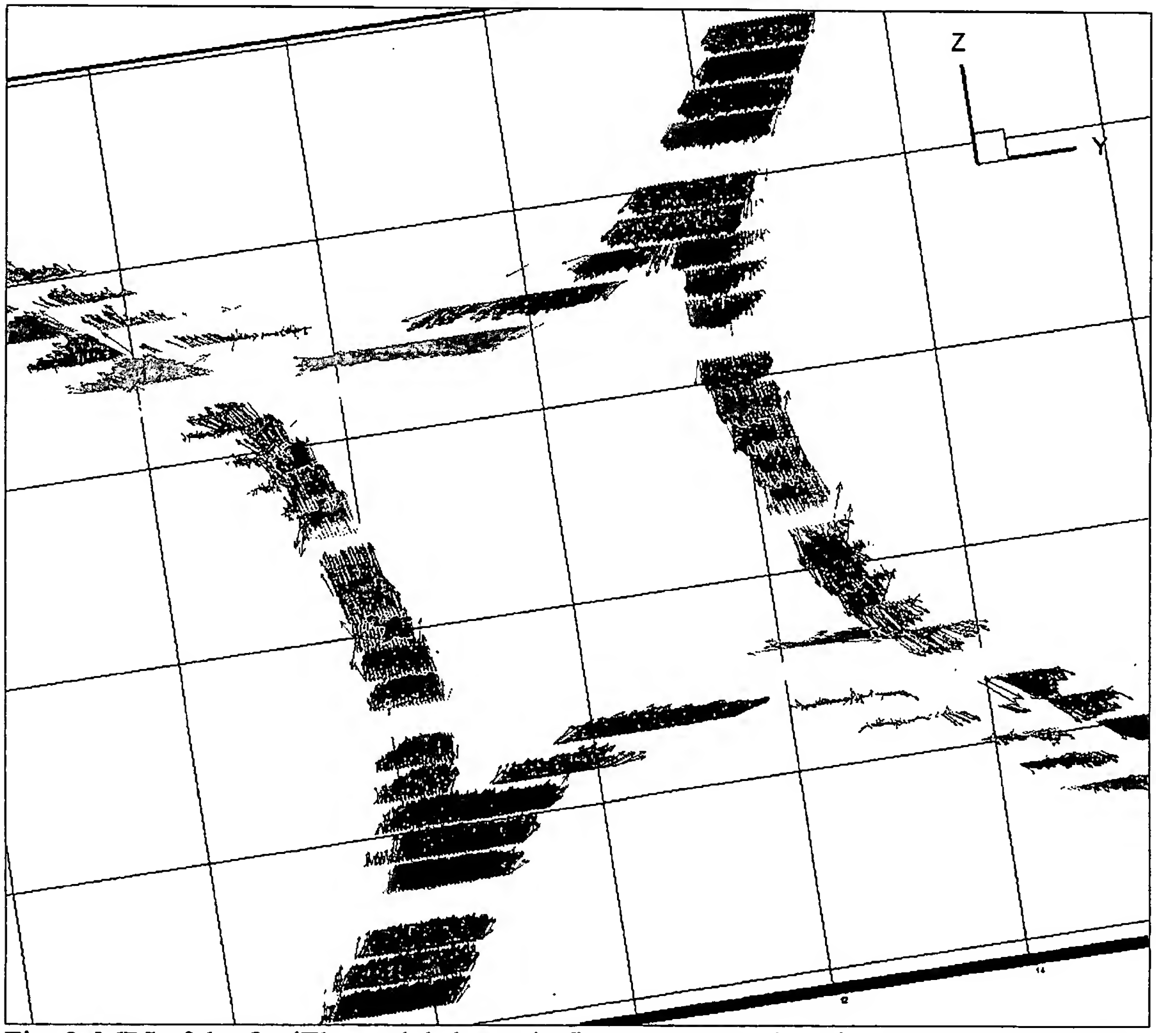

Fig. 8 MRI of the OptiFlo model shown in fig. 7. A water/glycerin solution was flowing through with a total flow through the model of 4 L/min. The figure shows the velocity vectors in all three directions of the flow and these are acquired in a stack of slices angled obliquely to the in-flow and out-flow directions. Some velocity vectors are missing in the outlets and this is due to a badly chosen velocity encoding, which results in the MRI scanner not being able to acquire the highest velocities. Hence, these don't show up in the data.

It is seen that there is a very nicely uniformly distributed velocity field causing no turbulence, swirling, or stagnant flow; basically a perfect optimally power loss reduced flow.

Furthermore, Particle Image Velocimetry experiments of the model in fig. 7, which unfortunately have not yet been finally processed, showed similar results of the flow field shown in Fig. 8.

Note:

This invention was disclosed to a post doc from University of North Carolina, Brooke Steele, Ph.D on January 12, 2004. When disclosed to her, she said that she thought about a similar connection in November, 2003 and disclosed it to her advisor at University of North Carolina.

This invention has also been disclosed to several people in the Children's Healthcare Of Atlanta community. A model was shown to Joseph Forbess, MD, James Parks, MD, and Kirk Kantor, MD.

The first time the idea of the OptiFlo was disclosed was in Dr. Ajit Yoganathan's research group, in 2002. Work was not begun until the middle of 2003.

WHAT IS CLAIMED:

1. An apparatus as described herein and as shown in the Figures, including each and every limitation and embodiment; and

2. A method of operation as described herein and as shown in the Figures, including each and every limitation and embodiment.